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09/701,140	11/21/2000	Brian Hawtin	2000-0702.OR	6011

7590

07/01/2003

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EXAMINER

WELLS, LAUREN Q

ART UNIT PAPER NUMBER

1617

DATE MAILED: 07/01/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/701,140

Applicant(s)

HAWTIN, BRIAN

Examiner

Lauren Q Wells

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,9,11-13,15,17,21-23,28 and 31 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

- 5) ☒ Claim(s) 13 is/are allowed.

- 6) ☒ Claim(s) 1,3-5,9,11,12,15,17,21-23,28 and 31 is/are rejected.

- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some \* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)

- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

- 5) ☐ Notice of Informal Patent Application (PTO-152)

- 6) ☐ Other:

### **DETAILED ACTION**

Claims 1, 3-5, 9, 11-13, 15, 17, 21-23 and 31 are pending. The Amendment filed 5/23/03, Paper No. 19, cancelled claims 10 and 30, and amended claims 1, 4, 11, 13, 17, 21, 23, and 28.

#### ***Response to Applicant's Arguments/Amendment***

The Applicant's arguments filed 5/23/03 (Paper No. 19) to the rejection of claims 1, 3-5, 9, 11-13, 15, 17, 21-23, 38, 31 made by the Examiner under 35 USC 103 have been fully considered and deemed not persuasive.

The Applicant's amendment to the claims and arguments filed 5/23/03 (Paper No. 19) are sufficient to overcome the 35 USC 112 rejections in the previous Office Action.

The Applicant's amendment to claim 13 filed 5/23/03 (Paper No. 19) places claim 13 in condition for allowance. Since the previous Office Action for reasons why this amendment places the claim in condition for allowance over the prior art.

#### ***103 Rejection Maintained***

The rejection of claims 1, 3-5, 10-12, 17, 23 and 28 under 35 U.S.C. 103(a) as being unpatentable over Totten et al. (GB 2202145) in view of Jacobs et al. (5,939,085) and Sang et al. (6,143,310) is MAINTAINED for the reasons set forth in the Office Action mailed 2/19/03, Paper No. 17, and those found below.

The rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over Totten et al. (GB 2202145) in view of Jacobs et al. (5,939,085) and Sang et al. (6,143,310) as applied to claims 1, 3-5, 10-12, 17, 23 and 28, and further in view of Dener et al. (WO 98/04537) and

Art Unit: 1617

Haider (1979) is MAINTAINED for the reasons set forth in the Office Action mailed 2/19/03, Paper No. 17, and those found below.

The rejection of claims 15 and 21 under 35 U.S.C. 103(a) as being unpatentable over Totten et al. (GB 2202145) in view of Jacobs et al. (5,939,085) is MAINTAINED for the reasons set forth in the Office Action mailed 2/19/03, Paper No. 17, and those found below.

The rejection of claim 31 under 35 U.S.C. 103(a) as being unpatentable over Totten et al. (GB 2202145) in view of Jacobs et al. (5,939,085) as applied to claims 15 and 21, and further in view of Sang et al. is MAINTAINED for the reasons set forth in the Office Action mailed 2/19/03, Paper No. 17, and those found below.

The rejection of claim 22 under 35 U.S.C. 103(a) as being unpatentable over Totten et al. (GB 2202145) in view of Jacobs et al. (5,939,085), as applied to claims 15 and 21 above, and further in view of Dener et al. and Haider is MAINTAINED for the reasons set forth in the Office Action mailed 2/19/03, Paper No. 17, and those found below.

Applicant argues, "Nowhere do the cited references, whether taken alone or in combination, teach or suggest the combination of an alkoxylated.cetyl alcohol and an amphoteric surfactant providing such an enhanced dermatological transmission vehicle for a polar drug". This argument is not persuasive, as it is not commensurate in scope with the instant claims which do not recite any enhanced properties. Furthermore, the Examiner respectfully points out that the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Art Unit: 1617

Applicant argues, "Applicant has diligently reviewed the cited prior art, and has found no teaching or incentive whatsoever to combine the surfactant of Jacobs et al. '085 with the dermatological composition of Totten et al. '145 to thereby obtain enhanced dermatological transmission of a polar drug as is presently claimed. Nowhere do the cited references teach or suggest enhanced dermatological transmission of a polar drug through the combination of an alkoxyated cetyl alcohol and an amphoteric surfactant". This argument is not persuasive. First, the Examiner respectfully points out that this argument is not commensurate in scope with the instant claims, as the instant claims do not recite any enhanced properties. Again, it is respectfully pointed out that the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Additionally, it is respectfully pointed out that there is motivation for adding the disodium cocoamphodiacetate of Jacobs et al. into the composition of Totten et al. because both references are directed to oil-in-water emulsions, wherein Jacobs et al. teach disodium cocamphodiacetate as imparting stability to the emulsion and as imparting smoothness to the skin.

Applicant argues, "the Examiner has consistently failed to address the fact that the cited references do not teach or suggest combining such components so as to obtain the medical advantages discovered in the present invention". This argument is not persuasive, as it is not commensurate in scope with the instant claims.

Applicant argues, "The unexpected nature of the presently claimed combination is demonstrated by the long felt need in the art for the development of an acceptable topical vehicle

Art Unit: 1617

which allows adequate skin transmission of a polar drug, and particularly sodium cromoglycate and nedocromil sodium". This argument is not persuasive, as Applicant has not provided a showing of long-felt need in the art. It is respectfully pointed out that the declarations concurrently submitted with these arguments are directed toward the unexpected benefits of the instant composition and not the long-felt need of the invention. The Examiner respectfully directs Applicant to MPEP 716.04, which states the guidelines for establishing long-felt need. In summary MPEP 716.04, states that the relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors: 1) the need must have been a persistent one that was recognized by those of ordinary skill in the art; 2) the long-felt need must not have been satisfied by another before the invention by Applicant; 3) the invention must in fact satisfy the long-felt need.

Applicant argues that the instant invention has achieved unexpected results. Two declarations have been submitted to demonstrate these unexpected results. However, the instant declarations are not sufficient to show unexpected results. The Examiner respectfully directs Applicant to the guidelines for showing unexpected results. It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, Applicant has

Art Unit: 1617

not demonstrated unexpected results over the closest prior art and has not provided evidence that the results are of statistical and practical significance. Additionally, the declaration submitted by Applicant is not commensurate in scope with the subject matter claimed. The Examiner respectfully suggests that Applicant provide a declaration comparing the instant invention with that of the closest prior art, Totten et al. In the declaration, Applicant should provide evidence that though polyproxylated cetyl alcohol and amphoteric surfactants are known to increase the solubility of active agents in an emulsion and are known to increase stability of an emulsion, these properties do not account for Applicant's unexpected enhancement in the dermatological transmission of sodium cromoglycate and nedocromil sodium.

#### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

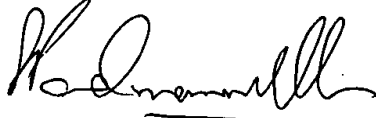
Art Unit: 1617

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-5:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
June 25, 2003

  
SREENI PADMANABHAN  
PRIMARY EXAMINER 6/27/03